

obviousness under 35 U.S.C. § 103 requires that the prior art both **suggest** the invention **and** provide one of ordinary skill in the art with **a reasonable expectation of success** in carrying out the claimed invention. In re Dow Chemical Co., 5 USPQ2d 1529 (Fed. Cir. 1988). In addition, as repeatedly stated by the Courts, any obviousness determination under § 103 must include an evaluation of the prior art in relation to **the claimed invention**. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 90 (Fed. Cir. 1986).

The law is clear that, in determining obviousness, the disclosures of prior art references must be viewed **in their entireties** for all that they teach including **"disclosures that may diverge from or teach away from the invention at hand."** W.L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 311 (Fed. Cir. 1983).

Furthermore, inherency is not a valid basis for a determination of obviousness under § 103: "the inherency of an advantage and its obviousness are entirely different questions; [t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." In re Shetty, 195 USPQ 753, 757 (CCPA 1977)(emphasis added). This law has been reiterated in numerous recent cases including In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993):

"Obviousness cannot be predicated on what is unknown [citations omitted]. Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection."

See also, Kloster Speedsteel AB v Crucible Inc., 230 USPQ 81, 88 (Fed. Cir. 1986).

The Office Action has held that the Boyle, et al. patent teaches a spinal implant made of bone with a superior end face, and inferior end face, and an outer side wall with at least two flat portions and two pin holes. The Office Action has held that while the Boyle, et al. patent does not teach that the hole is on each of the flat portions, it would be obvious to one having ordinary skill in the art, at the time the invention was made, to have a pin hole on each flat side. Further, the Office Action acknowledges that the Boyle, et al. patent fails to teach that the pin holes can be at an angle. A

conclusion is made that it would be obvious to one having ordinary skill in the art, at the time the invention was made, to construct the spinal implant with pin holes at an angle of 30°, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. However, the *In re Aller* reference pertains to a chemical case wherein the process was performed at temperatures between 40°C and 80°C with an acid concentration between 20% and 70% that was held to be *prima facie* obvious over another reference process that differed from the claims only in that the reference process was performed at a temperature of 100°C with an acid concentration of 10%. The court in *In re Aller* held that in order for the stated standard to be an appropriate consideration, the parameter must be first be recognized as being a result effective variable., i.e., a variable that achieves a recognized result before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In Re Antonie*, 559 F.2d 618. In other words, there must be some teaching or indication to one of skill in the art that this optimization should occur. It is not within the skill of one in the art to randomly take every single parameter of an invention and optimize every single parameter absent some teaching or suggestion to do so. It is respectfully submitted that there is absolutely no suggestion or teaching in the Boyle, et al patent for the optimization of the angle at which the pin holes are aligned. Further, there is no disclosure or suggestion for altering the holes at all. Instead, the holes are merely included for assistance in inserting the device.

The use of hindsight is absolutely forbidden because at the time of the invention there was no knowledge to those of skill in the art that optimization of the pin hole angle would be useful. In contradistinction, the presently claimed invention has determined that the 30° alignment is beneficial and critical for assisting in the insertion of the device. The angle is beneficial for properly inserting the device. The Boyle, et al. patent does not even disclose that there is an angle at which these two holes should be aligned. There would be no reason for one of skill in the art to consider altering the angles absent the presently pending application being filed. As such, the claims are

patentable over the prior art and reconsideration of the rejection is respectfully requested.

Claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentably obvious over the Ferreira, et al. patent publication in view of the Boyle, et al. patent. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over the Ferreira, et al. patent publication, in view of the Boyle, et al. patent is respectfully requested.

With regard to claim 13, the Office Action has held that the Ferreira, et al. patent publication teaches a spinal implant with a superior and inferior face with concentric cuts on both faces. The Office Action acknowledges that the Ferreira, et al. patent publication fails to teach that there are at least two flat side walls. The Office Action states that the Boyle, et al. patent teaches a spinal implant with at least two flat side walls and it would therefore be obvious to one skilled in the art to construct the invention to combine the concentric cuts on both faces from the Ferreira, et al. patent publication with the flat side walls of the Boyle, et al. patent. However, there is no suggestion for such a modification. Further, as the Ferreira, et al. patent publication was filed on August 20, 2002, claiming priority to an August 20, 2001, provisional patent application, which post dates the Boyle, et al. patent by almost one year, if such a suggestion would have been obvious then the inventors could have included such a modification in the patent application. The lack of inclusion is a very telling sign that the flat side walls were not desired. Further, paragraph 61 states that the spinal implant is generally cylindrically shaped having a planar and circular superior and a planar and circular inferior end. There is absolutely no suggestion that there should be any deviation from this. In order for an obviousness rejection to be appropriate, there must be some teaching or suggestion in the prior art for the combination of references. Absent such a suggestion, the obviousness rejection is improper as the combined references do not teach the device as recited in the presently pending independent claims. It is respectfully submitted that such a rejection is improper and reconsideration of the rejection is respectfully requested.

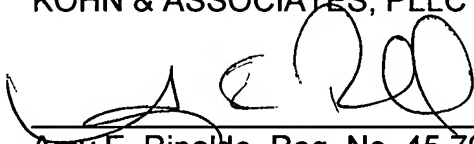
The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

The present amendment adds no new matter and all claims and amendments are supported by the specification. It is respectfully submitted that the present application is now in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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